UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

GIANT EAGLE, INC.,	)	
	)	
Plaintiff,	)	Civil Action No.
	)	
v.	)	
	)	
SOLVAY PHARMACEUTICALS, INC., ABBOTT PRODUCTS, INC., ABBVIE PRODUCTS, LLC, ABBVIE INC., UNIMED PHARMACEUTICALS, LLC, WATSON PHARMACEUTICALS, INC., ACTAVIS, INC., PAR PHARMACEUTICAL COMPANIES, INC., PADDOCK LABORATORIES, INC., AND PERRIGO COMPANY,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

COMPLAINT

Plaintiff Giant Eagle, Inc. ("Giant Eagle") brings this civil action against Defendants Solvay Pharmaceuticals, Inc., formerly known as Unimed Pharmaceuticals, LLC, then Abbott Products, Inc., and now known as AbbVie Products, LLC, a wholly owned subsidiary of AbbVie, Inc. (collectively referred to herein, together with their affiliates, as "Solvay"), Watson Pharmaceuticals, Inc., now known as Actavis, Inc. (collectively referred to herein, together with their affiliates, "Watson"), Par Pharmaceutical Companies, Inc. (collectively referred to herein, together with its affiliates, "Par"), and Paddock Laboratories, Inc., now known as Perrigo Company (collectively referred to herein, together with their affiliates, "Paddock"), for violations of federal antitrust laws. For its Complaint, Giant Eagle alleges as follows:

I. NATURE OF THE CASE

1. This litigation challenges Defendants' unlawful exclusion from the market of low-cost AB-rated generic substitutes for the brand name prescription drug AndroGel. Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive actions

which precluded less expensive generic equivalents of AndroGel from entering the market and extended Solvay's monopoly on the sale of AndroGel at least until 2015, denying Giant Eagle access to lower cost generic alternatives.

2. AndroGel[1] is a brand name hormone replacement drug marketed by Solvay for topical use as a testosterone replacement therapy ("TRT") for males with a deficiency or absence of endogenous testosterone. The active ingredient in AndroGel is synthetic testosterone, which has not been under patent protection for decades. By 2006, AndroGel was Solvay's top selling product, with U.S. annual sales in excess of $400 million.

3. Brand name drugs and their generic versions contain the same active ingredient, and generics are found by the Food and Drug Administration ("FDA") to be just as safe and effective as brand drug counterparts. The only material difference between generics and brand name drugs is the price. In those instances where there is one generic competitor, generics are usually less expensive than their brand name counterparts. Furthermore, the discount usually increases significantly when multiple generic competitors exist in the market.

4. Solvay knew that, under the Hatch-Waxman Act, the new dosage exclusivity of brand name AndroGel was set to expire on February 28, 2003, and Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of AndroGel were likely to be filed, after which generic manufacturers and sellers would market those generic versions. Based on this knowledge, Solvay improperly obtained a patent—Patent No. 6,503,894 (the "'894 patent")—and used it as a platform to expand its market exclusivity.

5. As expected, in 2003, generic drug manufacturers Watson and Paddock notified Solvay that they intended to sell AB-rated generic versions of AndroGel. In response, Solvay

[1] Unless otherwise noted, all references to "AndroGel" herein are references to AndroGel 1.0%.

sued Watson and Paddock for infringing the '894 patent. In the ensuing litigation, each of the generic companies vigorously asserted that: (1) its product was outside the scope of Solvay's '894 patent, (2) the '894 patent was invalid, and (3) Solvay withheld important information from the United States Patent and Trademark Office ("PTO") in obtaining the '894 patent.

6. Notably, had the above-referenced patent litigation proceeded, *Solvay's patent was unlikely to prevent generic entry*. Accordingly, Paddock would have received final approval on or about the time the FDA granted tentative approval to market its AndroGel product—i.e., October 27, 2004. Regarding Watson, it could and would have begun marketing its generic AndroGel product upon receiving FDA approval, which would have occurred no later than January 27, 2006.

7. Prior to trial in the patent litigation, the Generic Defendants recognized that it would be more economically beneficial to cooperate and share in Solvay's monopoly profits rather than compete with Solvay. Solvay's own financial analysis highlighted this dynamic. From this analysis, Solvay knew that it would need to pay the generic firms to agree to stay off the market until 2015 (Solvay's desired generic entry date). Solvay knew that—because eliminating price competition would preserve its monopoly profits—it could comfortably afford to pay the generic firms to delay their entry until 2015.

8. In the end, Watson and Par/Paddock (and their successors-in-interest) agreed to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost AB rated generic products to compete with AndroGel for nine years. As part of the agreement, Defendants Solvay, Watson, and Par/Paddock entered into anticompetitive agreements whereby Solvay agreed to give the Generic Defendants large and unjustified payments of millions of dollars, as well as other compensation, in exchange for their agreement

not to sell their AB-rated generic version of AndroGel at least until 2015. During this period of exclusivity Solvay then converted existing and future sales of AndroGel to its new product, AndroGel 1.62%[2], so that any AB-rated generic AndroGel product that might eventually be introduced would not be substitutable.

9. But for these unlawful actions, Watson and/or Par/Paddock would have begun marketing a generic AndroGel product far sooner than August 2015, and prior to the time Solvay was able to convert sales of AndroGel to its AndroGel 1.62% product. Through this conduct, Defendants have eliminated, restrained, and suppressed competition in the AndroGel market through 2015 and maintained or contributed to the maintenance of an unlawful monopoly in the AndroGel market in violation of federal antitrust laws.

10. The unlawful monopoly permits the charging of supracompetitive prices for AndroGel, which caused Giant Eagle, with and through its assignor, to be overcharged millions of dollars on its AndroGel purchases made during the foreclosure period.

11. As a direct and proximate result of Defendants' conduct, Giant Eagle, with and through its assignor, has been denied the benefits of free and unrestrained competition in the AndroGel market. Specifically, Giant Eagle, with and through its assignor, has been denied the opportunity to choose between brand name AndroGel and AB-rated generic versions, which would have been priced well-below AndroGel's monopoly prices.

II. JURISDICTION AND VENUE

12. This action arises under Section 1 of the Sherman Act, 15 U.S.C. §1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §15(a) and §26, for injunctive relief and to recover treble

[2] In 2011, Solvay launched it 1.62% testosterone product. Since the launch of AndroGel 1.62%, Solvay has shifted their promotional efforts to the reformulated version of the drug. As of March 2013, approximately two-thirds of all AndroGel prescriptions had correspondingly shifted from AndroGel 1% to AndroGel 1.62%.

damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Giant Eagle and its assignor as a result of Defendants' unlawful foreclosure of the United States market for synthetic testosterone gel. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §15.

13. Defendants transact business within this district, and they carry out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c) and 28 U.S.C. § 1407.

III. TOLLING OF THE STATUTE OF LIMITATIONS

14. Pursuant to Section 5(i) of the Clayton Act, also known as the Tunney Act, 15 U.S.C. § 16(i), the limitations period applicable to this action has been suspended since the Federal Trade Commission instituted proceedings based on some of the matters complained of in this action.

15. The limitations period applicable to Giant Eagle's claims also has been tolled since the filing of the first direct purchaser class action on behalf of a class of purchasers that includes Giant Eagle and/or its assignor.

IV. THE PARTIES

16. Plaintiff Giant Eagle, Inc. ("Giant Eagle") is a Pennsylvania corporation with its principal offices located at 101 Kappa Drive, Pittsburgh, PA. Giant Eagle is the parent company of the Tamarkin Company ("Tamarkin"), an Ohio corporation, and Riser Foods Company ("Riser"), a Delaware corporation. Giant Eagle, together with its wholly owned subsidiaries Tamarkin and Riser, is engaged in the retail supermarket and pharmacy business and owns, operates, and licenses at least 216 pharmacies. Giant Eagle purchases substantial quantities of pharmaceutical products and other goods for resale to the public.

17. During the relevant period of time, Giant Eagle purchased AndroGel from wholesaler McKesson Corporation ("McKesson"). McKesson purchased AndroGel directly from Solvay, and has assigned to Giant Eagle the antitrust claims arising out of McKesson's purchases of AndroGel that were subsequently resold to Giant Eagle. Giant Eagle brings this action in its own right and as the assignee of McKesson.

18. At all relevant times, Defendant Unimed Pharmaceuticals, LLC ("Unimed") was a wholly owned subsidiary of Defendant Solvay Pharmaceuticals, Inc. On or about February 16, 2010, Defendant Abbott Products, Inc. ("Abbott") acquired Solvay Pharmaceuticals, Inc. On or about January 1, 2013, Abbott spun off its pharmaceutical business to Defendant AbbVie, Inc. ("AbbVie"), a Delaware corporation with its principle place of business located at 1 North Waukegan Road, North Chicago, Illinois 60064. Defendant AbbVie Products, LLC ("AbbVie Products") is a wholly owned subsidiary of AbbVie. (Defendants Solvay Pharmaceuticals, Inc., Unimed, Abbott, AbbVie, and AbbVie Products are collectively referred to herein, together with its affiliates, as "Solvay"). Solvay is engaged in the distribution and sale of branded pharmaceutical products, including AndroGel. Solvay negotiated and/or approved Unimed's relevant unlawful agreements concerning AndroGel. In the twelve months ending December 31, 2007, Solvay's net pharmaceutical revenues from the sale of AndroGel in the United States were over $400 million.

19. Defendant Watson Pharmaceuticals, Inc. is now known as Actavis, Inc. ("Actavis") (Watson and Actavis are referred to herein, together with their affiliates, as "Watson"). Watson acquired Actavis in October 2012. Watson is a Nevada corporation with its principle place of business in Parsippany, New Jersey. Watson principally develops, manufactures, and markets generic versions of brand name drugs.

20. Defendant Par Pharmaceutical Companies, Inc. (together with its affiliates, "Par") is a Delaware corporation with its principle place of business in Woodcliff Lake, New Jersey. Par principally develops, manufactures, and markets generic versions of brand name drugs.

21. Defendant Paddock Laboratories, Inc. is now known as Perrigo Company ("Perrigo") (Paddock and Perrigo are referred to herein, together with its affiliates, as "Paddock"). Paddock (Perrigo) is a Delaware corporation with a principle place of business in Allegan, Michigan. Paddock principally develops, manufactures, and markets generic versions of brand name drugs.

22. The term "Generic Defendants" refers to Defendants Watson, Par, and Paddock.

23. The term "Defendants" refers to all the defendants.

24. All of the Defendants' actions described in this Complaint are part of, and were in furtherance of, the illegal monopolization and restraints of trade described herein, and were authorized, ordered, or done by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

V. BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

25. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-92. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

26. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

27. The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability. The FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

1. **The Hatch-Waxman Amendments**

28. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may now file an abbreviated new drug application ("ANDA"). ANDAs rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, known as showing that the generic drug is "bioequivalent" to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[3]

[3] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing

29. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Thus, for drugs that are intended to be absorbed into the bloodstream, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

30. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of legitimate (non-patent infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

31. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand name pharmaceutical companies.

2. **Paragraph IV Certifications**

32. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

(i) that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

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regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 CFR 314.54.

(ii) that the patent for the brand name drug has expired (a "Paragraph II certification");

(iii) that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

(iv) that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

33. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval" when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay, but it cannot authorize the generic manufacturer to go to market prior to one of these conditions occurring.

34. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is

entitled to 180 days of market exclusivity. Accordingly, the first-filing generic in such cases will be the only available generic for at least six months.

35. The ability of brand name manufacturers to delay FDA approval of an ANDA for up to 30 months merely by filing suit upon receipt of notice of a Paragraph IV certification is a strong incentive for brand name manufacturers to list patents in the Orange Book even if such patents are not eligible for listing, and to then sue any generic competitor that files an ANDA with Paragraph IV certifications even if the competitor's product would not actually infringe the listed patents.

3. **The Exclusivity Bottleneck**

36. The first generic applicant can help the brand manufacturer protect its monopoly not only by delaying its own market entry, but also by helping to delay the market entry of all other generic manufacturers. The first generic applicant and brand manufacturer can do this by agreeing that the generic applicant will delay marketing its generic drug but retain its 180-day exclusivity once it does begin marketing its generic product. Because the 180 days does not begin running until the generic applicant begins marketing (barring forfeiture, discussed further below), this tactic can delay the end date of the 180-day period of generic market exclusivity (a tactic called exclusivity "parking"). This sort of agreement thereby creates a "bottleneck" because later generic applicants cannot launch until after the first generic applicant's 180-day exclusivity has finally elapsed (or is forfeited).

37. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). In relevant part the MMA attempts to make it more difficult for brand and generic pharmaceutical companies to conspire to delay

the end of the first-filer's 180-day period of generic market exclusivity by outlining a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity.

38. Under the "failure to market" provision in the MMA, the first ANDA applicant will forfeit its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

39. Despite the intended effects of the MMA, brand name manufacturers and first-filing generics are able to structure their anti-competitive agreements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place. For example, brand name manufacturers and first-filing generics may settle their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seek a consent judgment settling the litigation that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed.

40. When the brand manufacturer and first-filing generic reach such an agreement, in order to trigger a forfeiture and gain access to the market, subsequent ANDA applicants must first obtain a judgment that all the patents for which the first-filing generic company filed Paragraph IV certifications are invalid or not infringed. Obtaining such a judgment may require

the subsequent ANDA applicant to initiate a declaratory judgment action over patents included in the first-filing generic's Paragraph IV certification but which the brand company did not assert against the subsequent generic in its own Paragraph IV litigation.

41. Therefore such agreements between the brand manufacturer and the first-filing generic create additional barriers to entry by other generic companies that would not exist but for their agreement. The brand manufacturer and first-filing generic can make attempted entry by additional generic manufacturers even less attractive by structuring their agreement such that in the event the 75-day clock is triggered by another generic manufacturer's successful litigation, the first-filing generic can then enter, preserving its 180-day exclusivity period and delaying entry by the successful generic litigant. And because the expected profitability of generic entry may decrease with each additional generic entrant after the first, particularly when the first has an exclusivity period, raising the fixed costs of entry while lowering the potential profits in the event of successful entry can effectively deter additional generic manufacturers from attempting entry.

B. The Benefits of Generic Drugs

42. Typically, AB-rated generics cost much less than their branded counterparts. Since the passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies, like those operated by Giant Eagle, to substitute AB-rated generic equivalents for branded prescriptions unless the prescribing physician has specifically ordered otherwise.

43. Once a generic equivalent hits the market, the generic quickly takes sales from the branded drug. More than 90 percent of prescriptions for drugs that are available in both branded and generic forms are filled with a generic.

44. The speed at which market prices fall and generic shares increase can depend on the number of generic entrants. Typically the branded drug will lose share to generics faster, and market prices will fall more quickly, if there is more than one generic entrant.

45. Branded manufacturers are well aware of generics' steady erosion of their previously-monopolized market. Branded manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to illegal means, including the sort of payment agreements described herein whereby a branded manufacturer pays its potential generic competitors to both delay their own entry and also to help raise barriers to entry by other generic companies.

VI. FACTS

A. Solvay's AndroGel Prescription Drug

46. Solvay markets branded prescription AndroGel. AndroGel is a pharmaceutical gel containing synthetic testosterone. Testosterone was first artificially synthesized in 1935 and has been available in various drug products since the 1950s. Pharmaceutical gel products like AndroGel have been available for decades.

47. In August of 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used in AndroGel from the Belgian pharmaceutical company Besins Healthcare S.A. (together with its affiliates, "Besins"), which had developed the formulation. At the same time, Besins agreed to provide a commercial supply of AndroGel to Solvay after the FDA approved the product for sale.

48. Solvay filed a U.S. NDA for AndroGel in April of 1999, which the FDA approved in February of 2000. The FDA approved AndroGel as a TRT for men with hypogonadism, which is often associated with advancing age, certain cancers, diabetes, and

HIV/AIDS, among other conditions, and can result in fatigue, muscle loss and erectile dysfunction.

49. AndroGel has consistently been Solvay's highest selling pharmaceutical product. From 2000 through 2007, cumulative U.S. sales of AndroGel totaled over $1.8 billion. In 2007 alone, U.S. sales of AndroGel exceeded $400 million, representing one-third of Solvay's U.S. pharmaceutical revenue.

50. On information and belief, Solvay sells AndroGel at prices far above Solvay's cost of obtaining the product from Besins, making AndroGel highly profitable for Solvay. Even accounting for other direct expenses Solvay allocates to selling and marketing AndroGel, Solvay's profit margin on AndroGel net sales is substantial.

B. Solvay's Prosecution of the '894 Patent

51. On August 30, 2000, five years after Solvay licensed AndroGel from Besins, and months after receiving FDA approval to market AndroGel in the United States, Solvay and Besins applied for a U.S. patent relating to AndroGel. The patent did not claim synthetic testosterone itself or methods of using testosterone generally, but rather covered the use of a particular pharmaceutical gel formulation containing testosterone and other specified ingredients in specified amounts.

52. The United States Government Accountability Office has reported that patent examiners are generally expected to process an average of 87 patent applications per year and have time quotas of 19 total hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an *ex parte* process in which patent examiners rely upon the information and candor of applicants. The vast majority of all patent applications are ultimately granted.

53. The patent application relating to AndroGel contained multiple disclosure statements identifying more than 400 articles and patents discussing previous testosterone and hormone therapies, together with copies of each of these articles and patents in multiple notebooks, compromising more than three feet of materials for the examiner to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

54. The patent Solvay prosecuted was issued on January 7, 2003 as Patent No. 6,503,894. The patent is directed to pharmaceutical compositions containing testosterone gel formulations and methods of using these compositions to treat hypogonadism.

55. None of the originally filed claims in Solvay's patent application recited sodium hydroxide, whose chemical symbol is "NaOH."

56. Indeed, the sole reference to sodium hydroxide in the entire specification appear in Table 5 (reproduced below), which discloses a single formulation having a specific amount (4.72 grams) of a specific sodium hydroxide solution (0.1 N NaOH).

TABLE 5

Composition of AndroGel®

SUBSTANCE	AMOUNT (w/w) PER 100g OF GEL
Testosterone	1.0g
Carbopol 980	0.90g
Isopropyl myristate	0.50g
0.1 N NaOH	4.72g
Ethanol (95% w/w)	72.5g
Purified Water	100.0g

57. The phrase "0.1 N" indicated that the sodium hydroxide is in a dilute aqueous solution (roughly 4 grams of sodium hydroxide per 1000 grams of solution), as opposed to the pure (anhydrous) form of sodium hydroxide. 4.72 grams of a 0.1 N NaOH solution contains approximately 0.019 grams of sodium hydroxide and approximately 4.70 grams of water. Thus, the overall concentration of sodium hydroxide concentration in the AndroGel formulation

described in Table 5 was roughly 0.019 percent (0.019 grams in a total of 100 grams of formulation).

58. On October 29, 2001, Solvay filed an Amendment with the PTO that cancelled certain originally-filed claims and added new dependent claims 45 and 64. In both of these new dependent claims, the term "sodium hydroxide" appears alone without any indication of either (a) a range (e.g., "about 1% to about 5%") or (b) a modifier indicating that the recited amount reflected the weight of a dilute solution (e.g., "0.1 N") rather than the weight of pure (anhydrous) sodium hydroxide. The remarks in Solvay's submission did not mention either these dependent claims or sodium hydroxide.

59. On or about December 21, 2001, Solvay filed a Supplemental Amendment, cancelling dependent claims 45 and 64 and adding new claims. On February 2, 2002, Solvay filed a Second Supplemental Amendment, changing all independent claims but one contained in the patent.

60. The February 2, 2002 Second Supplemental Amendment changed all independent claims (except for one) to recite weight ranges for pure (anhydrous) sodium hydroxide, *i.e.*, "about 1% to about 5%" and "about 1% to about 3%." None of those proposed claims referred to the weight ranges as referring to a dilute solution (i.e., 0.1 N). As support for these claims, Solvay cited Table 5 and stated: "Note that 4.72g of 0.1 NaOH = 1.8g NaOH in 100g of gel, or about 1.8%." By making that statement—i.e., by converting the 4.72 grams of a 0.1 N solution of sodium hydroxide in AndroGel to a measure of pure (anhydrous) sodium hydroxide—Solvay demonstrated its intent to express the sodium hydroxide limitation in the claims as pure sodium (anhydrous) hydroxide rather than as a 0.1 N solution. The remarks did not otherwise mention sodium hydroxide.

61. While the 1.8 NaOH in 100g of gel is within the ranges of "about 1% to about 5%" and "about 1% to about 3%" recited in the then newly-added claims, there was no other calculation involving sodium hydroxide supplied by Solvay supporting this range.

62. Significantly, the calculation converting the 4.72g of 0.1 NaOH to its equivalent amount in pure form in the AndroGel composition was in error by a factor of roughly 100. That is, the equivalent amount of pure sodium hydroxide in the AndroGel composition in Table 5 is not 1.8 grams, but rather about 0.019 grams, per 100 grams of gel.

63. Subsequent to filing the Second Supplemental Amendment, Solvay further amended the claims reciting sodium hydroxide on two separate occasions, but on neither occasion did Solvay seek to amend the claims to recite the ranges for sodium hydroxide in a solution by inserting "0.1 N" or the like.

64. As a result of Solvay's prosecution of the patent: (a) the specification of the '894 patent application provides no written description support for any range of concentrations of sodium hydroxide (whether pure or in solution), and the sole mention of sodium hydroxide is a single concentration in a single formulation as reflected in Table 5; and (b) when claims 1, 9, 10, and 18 were later added reciting ranges of sodium hydroxide—additions for which there was absolutely no written description support—those ranges indisputably referred to ranges of amounts of pure (anhydrous) sodium hydroxide rather than ranges of amounts of a dilute sodium hydroxide solution such as 0.1 N.

65. The five independent claims (i.e., claims 1, 9, 10, 18, and 31) in the '894 patent issued on January 7, 2003 recited the following:

1. A pharmaceutical composition, consisting essentially of:

a. about 0.5% to about 10% testosterone;

b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
c. about 0.1% to about 5% isopropyl myristate;
d. about 1% to about 5% sodium hydroxide; and
e. about 0.1% to about 5% of a gelling agent,

wherein the percentages of components are weight to weight of the composition.

9. A hydroalcoholic gel formulation, consisting essentially of:

a. about 1% to about 2% testosterone;
b. about 50% to about 75% ethanol;
c. about 0.5% to about 2% isopropyl myristate;
d. about 1% to about 3% sodium hydroxide;
e. about 0.5% to about 2% polyacrylic acid; and
f. water in an amount sufficient to make the formulation 100%;

wherein the percentages of components are weight to weight of the formulation.

10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:

a. about 0.5% to about 5% testosterone;
b. about 30% to about 98% ethanol;
c. about 0.1% to about 5% isopropyl myristate;
d. about 1% to about 5% sodium hydroxide; and
e. about 0.1% to about 5% of a gelling agent;

wherein the percentages of components are weight to weight of the composition.

18. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a phannaceutical [sic] composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% of a gelling agent;
(iii) about 0.1% to about 5% isopropyl myristate;
(iv) about 1% to about 5% sodium hydroxide; and
(v) about 30% to about 98% alcohol selected form the group consisting of ethanol and isopropanol;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

31. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmnaceutical [sic] composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% isopropyl myristate;
(iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
(iv) about 0.1% to about 5% of a gelling agent;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

66. Thus, each of claims 1, 9, 10, and 18 specify that pure sodium hydroxide accounts for at least "about 1%" sodium hydroxide on a "weight to weight basis."

67. Within 30 days of the issuance of the '894 patent in January of 2003, Solvay submitted it for listing in the Orange Book, along with a declaration signed under oath, certifying that one or more of the issued claims covered AndroGel, or an approved method of using AndroGel, and that the '894 patent could reasonably be asserted against a person who engaged in the unauthorized manufacture, use, or sale of AndroGel.

68. The '894 patent expires in August of 2020. In addition, Solvay recently received regulatory exclusivity from the FDA based on pediatric studies that would provide Solvay with an additional six months of exclusivity beyond the expiration of its patent, through February of 2021.

C. Solvay Seeks a "Certificate of Correction"

69. On or about June 12, 2003, five months after the patent issued, Solvay requested that the PTO "correct" many claims of the '894 formulation patent. As Solvay knew, the '894 patent as issued did not cover the AndroGel product or likely generic equivalents that would be proposed in ANDAs filed with the FDA. This was because, like the FDA-approved AndroGel product, proposed generic products would not, and Watson and Paddock's generic versions of AndroGel did not, contain the concentration levels of pure sodium hydroxide required by the relevant claims of the '894 patent. Solvay knew that the compositions claimed in the relevant claims of the '894 patent would not be marketed by generic manufacturers because, as issued, the composition would be too caustic to be used on human skin. Generic manufacturers would seek to market an AB-rated equivalent of Solvay's AndroGel, which contained lower levels of sodium hydroxide than those required by the '894 patent.

70. To bring its existing AndroGel product within the claims of the '894 patent, Solvay filed a Request for a Certificate of Correction ("COC") with the PTO. In it, Solvay requested the insertion of a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Despite this material change, Solvay falsely represented to the PTO that this "correction" would not "alter the substance of the patent in any way that would necessitate reevaluation by an Examiner." Solvay further misrepresented that "the mistakes were made in good faith and that the proper language is

contained throughout the specification," even though the desired language, a reference to "0.1N NaOH", appeared only once in the specification within Table 5.

71. Six months later, on December 16, 2003, the PTO issued a COC. As "corrected," the five independent claims recite:

> 1. A pharmaceutical composition, consisting essentially of:
> a. about 0.5% to about 10% testosterone;
> b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;
> c. about 0.1% to about 5% isopropyl myristate;
> d. about 1% to about 5% 0.1 N sodium hydroxide; and
> e. about 0.1% to about 5% of a gelling agent;
>
> wherein the percentages of components are weight to weight of the composition.
>
> 9. A hydroalcoholic gel formulation, consisting essentially of:
>
> a. about 1% to about 2% testosterone;
> b. about 50% to about 75% ethanol;
> c. about 0.5% to about 2% isopropyl myristate
> d. about 1% to about 3% 0.1 N sodium hydroxide;
> e. about 0.5% to about 2% polyacrylic acid; and
> f. water in an amount sufficient to make the formulation 100%;
>
> wherein the percentages of components are weight to weight of the formulation.
>
> 10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:
>
> a. about 0.5% to about 5% testosterone;
> b. about 30% to about 98% ethanol;
> c. about 0.1% to about 5% isopropyl myristate;
> d. about 1% to about 5% 0.1 N sodium hydroxide; and
> e. about 0.1% to about 5% of a gelling agent;
>
> wherein the percentages of components are weight to weight of the composition.

18. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical [sic] composition consisting essentially of:
(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% of a gelling agent;
(iii) about 0.1% to about 5% isopropyl myristate;
(iv) about 1% to about 5% 0.1 N sodium hydroxide; and
(v) about 30% about 98% alcohol selected from the group consisting of ethanol and isopropanol; wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject so as to achieve a serum concentration within a range between about 300 ng testosterone per dl serum to about 1050 ng testosterone per dl serum within at least about 36 hours of daily dosing of the composition.

31. A method for administering an active agent to a human subject in need thereof, the method comprising:

a. providing a pharmaceutical composition consisting essentially of:

(i) about 0.5% to about 5% testosterone;
(ii) about 0.1% to about 5% isopropyl myristrate;
(iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and
(iv) about 0.1% to about 5% of a gelling agent;

wherein the percentages are weight to weight of the composition; and

b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

72. A COC applies only to causes of action that arise *after* the issuance of the COC.

This rule reflects the policy that issuance of a patent serves a public notice function; patentees

have a duty to carefully prepare their patent applications and then to police their patents when issued for accuracy and correctness.

73. Pursuant to 35 U.S.C. § 271(3)(2)(A), the filing of an ANDA constitutes an act of infringement. Thus, in this instance, the infringement claims that arose by operation of Watson and Paddock filing their ANDAs arose in May 2003, when the ANDAs were filed, prior to issuance of the COC. As a matter of law, the COC was inapplicable to Solvay's infringement litigation against Watson and Paddock. Solvay was precluded from invoking the "corrected" patent claims contained in the COC in those suits. As a result, because the claims of the '894 patent as issued did not apply to AndroGel or AB generic versions thereof, neither Watson's nor Paddock's generic version of AndroGel infringed the '894 patent.

74. In any event, as discussed below, even if the claims "corrected" by the COC were applicable in Solvay's suits against Watson and Paddock, the "corrected" claims were invalid.

D. Solvay Asserts the Invalid '894 Patent

75. As discussed above, on January 7, 2003, less than two months before its exclusivity was to expire, Solvay obtained U.S. Patent No. '894 and immediately had it listed in the Orange Book as applying to AndroGel.

76. In its fervor to expedite issuance of the '894 patent, Solvay botched its prosecution, obtaining a patent that did not apply to AndroGel or its likely generic equivalents. As a result, the '894 patent was not properly listed in the Orange Book or infringed by the products that were the subject of Watson's and Paddock's ANDAs. In addition, many of the claims in the '894 patent were clearly invalid and could not reasonably be asserted against the ANDA filers for that reason. Furthermore, in its desperation to "correct" the fatal defects in its '894 patent, Solvay misrepresented facts regarding the '894 patent to the PTO.

77. At the time it submitted the '894 patent for listing in the Orange Book, the '894 patent was improperly listed. The FDA regulations in effect at the time provided that "[f]or patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." 21 C.F.R. § 314.53. The then-existing claims of the '894 patent did not support listing in the Orange Book because (a) the '894 patent did not claim AndroGel (or the testosterone drug substance that is a component of AndroGel) or (b) an approved method of use for AndroGel. Claims 1-30 of the '894 patent (as well as "corrected" versions of those claims) were also invalid because there was no written description support for the sodium hydroxide range stated therein. Solvay knew that its efforts to convince the Patent and Trademark Office ("PTO") to issue a patent prior to the expiration of AndroGel's dosage exclusivity had resulted in errors that prevented the '894 patent from applying to AndroGel or an approved method of using AndroGel.

78. It is well settled law that "[o]ne who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that [independent] claim." *Wahpeton Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 (Fed. Cir. 1989). As a result, unless AndroGel (or an approved method of using AndroGel) fell within the scope of one of the five originally issued independent claims (claims 1, 9, 10, 18, and 31) of the '894 patent, it could not fall within the scope of any of the remaining dependent claims in the '894 patent.

79. Prior to the issuance of the COC, claims 1, 9, 10, and 18 required a formulation or composition having at least "about 1%" sodium hydroxide. As Solvay admitted in its pleadings in the patent litigation against Watson and Paddock, the phrase "sodium hydroxide" in the uncorrected '894 patent claims means the pure (anhydrous) form of sodium hydroxide. In addition, Solvay admits that the amount of sodium hydroxide recited in those claims is 50 to 250 times greater than the amount of sodium hydroxide in AndroGel. Therefore, Solvay could not assert that claims 1, 9, 10, or 18, as they existed at the time the infringement suits were filed, covered either AndroGel, the testosterone drug substance that is a component of AndroGel, any generic version of AndroGel, or an approved method of use for AndroGel or any generic version thereof. In fact, Solvay admits that a skilled pharmaceutical chemist would recognize that the amount of pure (anhydrous) sodium hydroxide recited in originally-issued claims 1, 9, 10, and 18 "is far too caustic" and would do damage to the human skin. Thus, Solvay knew the independent claims 1, 9, 10, or 18, and their dependent counterparts, did not apply to AndroGel and the inclusion of the '894 patent in the Orange Book was unlawful.

80. The sole remaining independent claim, claim 31, likewise could not reasonably be construed to cover a method for using AndroGel or a generic version thereof. Claim 31 requires, among other things, a "pharmaceutical composition consisting essentially of: (i) about 0.5% to about 5% testosterone; (ii) about 0.1% to about 5% isopropyl myristate; (iii) about 30% to about 98% of an alcohol selected from the group consisting of ethanol and isopropanol; and (iv) about 0.1% to about 5% of a gelling agent." The phrase "consisting essentially of" indicates that a claim "necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Thus, for a particular pharmaceutical

composition to meet the limitations of claim 31, it (a) must include the listed ingredients in the required amounts and (b) must exclude any additional ingredient that materially affects the basic and novel properties of the invention. Solvay's own briefing admits that the basic and novel properties of the invention are the ability to produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients. Sodium hydroxide materially affects the basic and novel properties of the purported invention, because the Carbopol gelling agent in the AndroGel formulation will not function properly (and will not produce plasma levels of testosterone sufficient to be effective in the treatment of hypogonadal patients) in the absence of sodium hydroxide. Under these circumstances, claim 31 of the '894 patent clearly did not encompass a method for using AndroGel. Thus, neither claim 31, nor any claims depending on it, could have justified Solvay's submission of the '894 patent for listing in the Orange Book.

81. At the time Solvay filed patent infringement suits against Watson and Paddock, the use or sale of the generic AndroGel products—that were the subjects of the Generics' ANDAs—clearly did not infringe the existing claims of the '894 patent. The proposed generic AndroGel products did not contain anywhere near the sodium hydroxide levels required by independent claims 1, 9, 10, and 18 of the '894 patent. As Solvay admitted, that amount of pure sodium hydroxide "is far too caustic" and would do damage to human skin. Thus, the Generics' ANDA products could not reasonably contain the amount of sodium hydroxide required by these claims.

82. Solvay had no basis for asserting claims 1, 9, 10, and 18 (and their dependent claims) against the Generic Defendants as reflected in its June 12, 2003 filing of a Request for Certificate of Correction. Thus, no later than June 12, 2003, Solvay knew its claims were defective and could not be asserted against Watson and Paddock. Likewise, Solvay knew of the

defect in the sole remaining independent claim 31—namely, the combination of a narrow transition phrase ("consisting essentially of") and the absence of a limitation reciting sodium hydroxide (or another appropriate base) and water, critical components of the AndroGel formulation and the proposed generic versions of AndroGel.

83. Solvay's contention that the certificate of correction ("COC"), which did not issue for several months after Solvay filed suit, cured its impropriety, is frivolous. It is black letter law that a COC is "not effective" for "causes arising before its issuance." *Southwest Software, Inc. v. Harlequin, Inc.*, 226 F.3d 1280, 1294 (Fed. Cir. 2000). The Federal Circuit reaffirmed this well-settled statutory principle the week before the COC for the '894 patent issued. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1353 (Fed. Cir. 2003) ("For causes of action that arise before the correction becomes effective, the patent must be considered without the benefit of the certificate of correction."). Thus, Solvay's certificate of correction was not effective for litigation instituted in August 2003, which asserted a cause of action that arose upon the filing of the ANDAs in May 2003.

84. Notably, Solvay's Claims 1-30 were invalid, either in their original or "corrected" form. Both sets of claims failed to comply with the written description requirement, and the "corrected" claims were invalid for the additional reason that Solvay was not entitled to the COC and had made misrepresentations to obtain it.

85. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). To satisfy the written description requirement, the disclosure of the specification must "convey with reasonably clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the

invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Claims 1-30, both in their original and "corrected" form, recite a range of sodium hydroxide weight-to-weight percentages. Solvay's application for the '894 patent, as originally filed, teaches no range of sodium hydroxide for a pharmaceutical composition. Instead, the sole reference to sodium hydroxide was a single weight-to-weight percentage in a single example in Table 5. When Solvay later added the claimed ranges, it accomplished the very thing the written description requirement forbids—namely, "later asserting that [it] invented that which [it] did not." *Amgen Inc.*, 314 F.3d at 1330. Nothing in Solvay's patent application could be viewed as conveying with reasonable clarity to those skilled in the art that, as of the filing of the application, the inventors were in possession of the ranges of sodium hydroxide later claimed, in either original or "corrected" form.

86. Moreover, even if the COC was relevant, Solvay was not entitled to the COC. Section 255 of the patent law permits the Patent Office to correct mistakes of "minor character" or mistakes of a "clerical or typographical nature." 35 U.S.C. § 255. A mistake that, if corrected, would broaden a claim scope cannot be of a "minor character." A broadening correction can only be made when it is "manifest" or "immediately apparent" and where it is "clearly evident" from the intrinsic evidence that such a correction is the one appropriate was to correct the error.

87. The "error" asserted by Solvay did not satisfy these requirements so the COC was invalid. Thus, even if the COC had been effective for the ANDA litigation (which it was not), it did nothing to bolster Solvay's infringement claims. Solvay also misrepresented the existence of written description support in its patent application to obtain the COC. Solvay represented to the PTO that "the mistakes were made in good faith" and that "the proper language is contained

throughout the specification, see for example, column 12, Table 5 ("0.1 N NaOH (sodium hydroxide)). . . . As such, the correction does not involve such changes in the patent that would constitute new matter or that would require reexamination." These misrepresentations were knowingly made to obtain the COC. The reference to "0.1 N NaOH" appeared only once in (not "throughout") the specification. Solvay's requested change also introduced "new matter" because the specification did not disclose any ranges for "0.1 N NaOH" as recited by the "corrected" claims.

F. Generic Companies Prepare to Challenge Solvay's '894 Patent

88. As discussed above, in May of 2003, Watson and Paddock each filed an application with the FDA for approval to market a generic version of AndroGel. As part of their ANDA applications, Watson and Paddock certified that their generic products did not infringe the '894 patent and that the patent was invalid.

89. Watson filed its ANDA before Paddock and was therefore eligible for 180-day exclusivity under the Hatch-Waxman Act.

90. With its ANDA, Paddock sought a partner to share the costs and risks associated with litigation, together with the rewards from a successful outcome. Paddock eventually reached a deal with Par Pharmaceuticals, Inc., which was a top-ten generic drug company and a veteran of pharmaceutical patent litigation. Under the deal, Par agreed to share litigation costs with Paddock, market Paddock's generic-product following launch, and share in the resulting profits.

91. On July 8, 2003, Watson notified Solvay that it filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid and/or not infringed. Paddock provided a similar Paragraph IV certification around that same time.

G. Solvay Files Patent Infringement Actions Against Watson and Paddock

92. Following the ANDA filings, in August, 2003, just weeks after filing for the COC, Solvay and Besins sued Watson and Paddock, alleging that each infringed the '894 patent by virtue of their ANDAs.

93. Before filing their complaints, Solvay's and Besins' only information relating to the Watson and Paddock products proposed in their ANDAs were the Paragraph IV notice letters, which detailed why their ANDAs and the proposed generic AndroGel products did not infringe the '894 patent.

94. Under the Hatch-Waxman Act, the lawsuits triggered automatic stays of final FDA approval for the proposed generic versions of AndroGel for thirty (30) months.

H. Watson and Paddock Initially Defend Against the Patent Litigation

95. As stated above, Solvay's patent infringement suits against Watson and Paddock would have likely failed, because (a) originally issued claims 1-30 of the '894 patent (as well as "corrected" versions of those claims) were invalid because there was no written description support for the sodium hydroxide range stated therein; (b) none of the issued claims could reasonably be interpreted as covering generic versions of AndroGel or a method of using generic AndroGel; (c) Watson and Paddock could not reasonably be viewed as infringing any of the "corrected" claims 1-30 of the '894 patent, because the certificate of correction was inapplicable to the litigation initiated before the certificate issued in December 2003 and because the certificate was invalid due to Solvay's misrepresentations to the PTO; and (d) claim 31 and its dependent claims could not reasonably be read to cover the use of Watson's or Paddock's AndroGel products, because Solvay excluded water and sodium hydroxide from claim 31.

96. Watson and Paddock both filed counterclaims seeking a declaratory judgment that their products did not infringe the '894 patent and/or that the patent was invalid.

97. Fact and expert discovery in the patent infringement litigation concluded in approximately July 2005.

98. Further recognizing the fatal flaws in the '894 patent, Watson and Paddock moved for summary judgment, seeking a finding that certain claims in the patent were invalid. They no doubt would also have moved for summary judgment of non-infringement following the claim construction rulings by the Court if not for the settlement reached with Solvay.

99. Summary judgment briefing between Solvay and Watson was completed on January 19, 2006, and the only summary judgment briefing that remained as of the date of settlement was the submission of Paddock's reply brief relating to invalidity.

100. Empirical studies have shown that when pharmaceutical patent infringement claims are tested in court, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which courts made final rulings on the merits of pharmaceutical patent claims (validity, infringement, or enforceability) found that alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generic applicants prevailed 73 percent of the time.

101. As a result of the facts and circumstances detailed above, the Defendants knew (or should have known) that Solvay would have lost the patent litigation on the merits.

I. Solvay Prepares for Generic Competition

102. Until a generic manufacturer enters the market, there is no bioequivalent drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supracompetitive prices without material loss to sales volume. Even after one generic enters the market, additional generic entrants typically increase the rate at which the brand share and market prices decrease, further shortening the period during which the brand can continue to charge supracompetitive prices. Consequently, brand name drug manufacturers have a strong interest in delaying the introduction of generic competition into the market, including delaying additional entrants.

103. Paddock's ANDA was tentatively approved by the FDA on October 27, 2004. Paddock's ANDA received final approval on May 23, 2007.

104. In late January of 2006, after the 30-month Hatch-Waxman stay expired, Watson's ANDA received final approval from the FDA, enabling Watson to market its AB-rated generic version of AndroGel. Watson was awarded 180 days of market exclusivity for being the first to file an ANDA for generic AndroGel containing a Paragraph IV certification.

105. Upon final FDA approval, Watson could launch its generic version of AndroGel on January 27, 2006, unless Solvay was able to obtain a preliminary injunction in the patent case to prevent Watson's launch. Prior to January 2006, Solvay had little incentive to settle the '894 patent litigation because the 30-month Hatch-Waxman stay was in effect, which protected AndroGel from generic competition.

106. Solvay recognized that additional generic competition would arise from approval of Paddock's ANDA. The CEO of Paddock's partner Par told investment analysts in February 2006 that if generic AndroGel did not launch in 2006, it "should certainly hit in 2007."

107. Despite the imminent threat of generic competition, Solvay did not seek to enjoin Watson's or Par/Paddock's launch because Solvay knew such an effort would be unsuccessful.

108. Instead, Solvay took action to (a) settle its patent litigations that had successfully delayed generic competition thus far, and (b) eliminate the threat of generic competition going forward without risking a potential adverse court decision.

109. On information and belief, in preparation for settlement negotiations with Watson and Par/Paddock, Solvay put together a financial model to analyze its settlement options, known internally as "Project Tulip." Solvay determined that it wanted to defer generic entry until 2015. The purpose of "Project Tulip" was to assess whether Watson and Par/Paddock would accept this delayed entry date by evaluating the Generics' expected return from continuing to litigate. From this analysis, Solvay concluded that Watson and Par/Paddock might agree to a settlement that delayed generic entry.

110. However, if Solvay wanted a settlement that delayed generic entry until 2015, it determined it would have to pay Watson and Par/Paddock for that delay. Solvay's analysis indicated it could easily afford to pay Watson and Par/Paddock not to compete and eliminate the near-term threat of generic entry. By delaying competition and maintaining supracompetitive pricing, Solvay, Watson, and Par/Paddock would collectively preserve monopoly profits, which could then be shared among themselves at the expense of the consumer savings that would have resulted from price competition. Even after paying a share of monopoly profits to Watson and Par/Paddock to secure their agreement not to compete, Solvay still expected to make more in AndroGel profits by delaying generic entry until 2015 than by continuing to litigate (and eventually lose) the patent lawsuits.

J. Solvay and Watson Enter into an Agreement Not to Compete

111. On information and belief, Solvay initiated discussions concerning a settlement of the litigation with Watson. The premise of the discussion was that Solvay would make a large payment to Watson as consideration for Watson not launching its generic product until Solvay's preferred entry date.

112. At the beginning of settlement negotiations, Watson proposed that Solvay could share AndroGel revenues with Watson through an arrangement under which Watson would "co-promote" AndroGel to doctors. Just months before, a consulting firm hired by Solvay had conducted a comprehensive analysis of Solvay's AndroGel promotion efforts. That analysis concluded that AndroGel co-promotion was unlikely to benefit Solvay, and in any event, Watson did not meet the set of criteria for potential co-promotion partners. Yet, because Solvay wanted to protect its monopoly for AndroGel until 2015, Solvay quickly agreed to consider allocating a portion of AndroGel profits to Watson through a pretextual co-promotion arrangement.

113. Watson was willing to accept Solvay's 2015 generic entry date only if it was compensated for that delay under the pre-textual "co-promotion" arrangement with a sufficiently large payment to outweigh its expected benefit from not agreeing to delay entry.

114. The amount of Solvay's payment to Watson also had to be large enough to compensate Watson for the risk posed by a planned new version of AndroGel—to be marketed by Solvay—that threatened to destroy the market for AndroGel 1.0% and make Watson's generic AndroGel product far less valuable by the time of Solvay's preferred entry date. Branded pharmaceutical companies frequently introduce a "line extension," or a new branded product that is related to but different from an existing product, to preserve sales of a branded franchise. In the case of AndroGel, Solvay planned to develop and market a testosterone gel containing 1.62% testosterone—more than the 1% testosterone contained in AndroGel—that would allow patients

to achieve similar therapeutic benefits with less gel. In 2011, Solvay launched its1.62% testosterone product. Since the launch of AndroGel 1.62%, Solvay has shifted their promotional efforts to the reformulated version of the drug. As of March 2013, approximately two-thirds of all AndroGel prescriptions had correspondingly shifted from AndroGel 1.0% to AndroGel 1.62%.

115. During settlement negotiations, Solvay informed Watson of its plans for its line extension product. Watson accepted Solvay's 2015 generic entry date even though by 2015, a line extension product could have a severe negative impact on its potential sales of generic AndroGel. Watson would not have accepted the 2015 generic entry date in light of these risks, absent the large payment from Solvay in the form of substantial sharing of AndroGel monopoly profits through the co-promotion deal.

116. On or about September 13, 2006, Solvay and Watson entered written agreements to settle their patent litigation. Under the parties' settlement, Watson agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date. Additionally, Watson agreed to forfeit its 180-day exclusivity on its ANDA.

117. Solvay and Watson simultaneously entered into a co-promotion deal that provided substantial compensation to Watson (the "S/W Co-Promotion Agreement"). Under the deal, Watson agreed to promote AndroGel to urologists, and Solvay agreed to share AndroGel profits with Watson. At the time it negotiated the deal, Solvay projected its annual payments to Watson would be between $15 and $30 million.

118. Solvay's payment to Watson was designed to be large enough—and it was large enough—to induce Watson to settle the AndroGel patent litigation and to agree to refrain from

marketing generic AndroGel until 2015. Rather than compete, Watson agreed to share in Solvay's AndroGel profits monopoly profits in exchange for Watson entering into a non-merit-based settlement of the'894 patent infringement suit. Because of the large payment offered by Solvay, Watson determined that it would be better off cooperating and sharing in Solvay's monopoly profits rather than by competing with its own generic product prior to the agreed entry date.

119. Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their settlement agreement or S/W Co-Promotion Agreement with the court; nor were the agreements contingent on court approval.

K. Solvay, Par, and Paddock Agree Not to Compete

120. On information and belief, under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

121. Par, like Watson, was willing to settle the AndroGel patent litigation with Solvay, and delay its entry to 2015, only if it received a large payment for that delay. During negotiations, Par quickly accepted Solvay's proposed 2015 generic entry date, contingent on the parties' ability to reach agreement on the value Par would receive in a settlement. That compensation was accomplished by means of a pretextual "co-promotion" agreement. In the words of a senior Par executive, Par was looking to "extract payments" from Solvay in settlement negotiations.

122. To agree on a value, Solvay and Par exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007. These forecasts discounted Par's generic AndroGel revenues to reflect Par's probability of prevailing in the patent litigation. According to a senior Solvay executive, Solvay developed these forecasts to "demonstrate to

[Par] what [its] options are, either to litigate or enter into these—this business arrangement . . . and if we entered into the business arrangement, we wouldn't be litigating. They go hand in hand."

123. Based on this financial analysis, Solvay and Par were able to "agree on a value" that Par would receive in exchange for settling the litigation. Solvay and Par agreed on the payments Par would receive *before* agreeing on what Par would do in exchange, other than defer generic entry until 2015. On May 13, 2006, Solvay and Par/Paddock confirmed via email their "agreed upon settlement of $12 million per year for 6 years coupled with manufacturing/ development and/or a co-promotion between Par and Solvay."

124. After the parties agreed on the amount that Solvay would pay Par, the parties met to discuss what type of business arrangement would accompany the settlement and how they would allocate the agreed-upon payments. The parties decided that Par would co-promote AndroGel to doctors and receive $10 million annually **(**the "S/PAR Co-Promotion Agreement"**)**, while Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million annually **(**the "S/PAD Back-Up Supply Agreement"**)**. As a Besins executive stated in an e-mail, a "backup manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market."

125. On September 13, 2006, the same day the Solvay/Watson agreements were signed, Solvay, Besins, Par, and Paddock entered written agreements to settle their patent litigation. Under the parties' settlement, Par and Paddock agreed to refrain from marketing generic AndroGel until February 28, 2016, or earlier if another generic company launched a generic version of AndroGel before that date.

126. At the same time Par signed its agreements with Solvay, it agreed to transfer $6 million upfront to Paddock through a transfer of title of Paddock's ANDA to Par. This large payment was necessary to obtain Paddock's assent to the settlement.

127. The payment that Solvay agreed to provide Par and Paddock was designed to be large enough—and was large enough—to induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2016. Rather than compete, Solvay, Par, and Paddock agreed to cooperate on AndroGel and share in monopoly profits. Because of the large payment offered by Solvay, Par and Paddock determined that they would be better off cooperating and sharing in Solvay's monopoly profits rather than by competing with their own generic product prior to the agreed entry date.

128. The district court hearing the patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment filed by the parties. As part of their settlement and in order to secure its large payments from Solvay, Paddock acknowledged that the '894 patent was valid and enforceable. Notably, the parties did not file their settlement agreement, S/Par Co-Promotion Agreement, or S/PAD Back-Up Supply Agreement with the court; nor were the agreements contingent upon court approval.

L. Solvay Paid Watson and Par/Paddock Through Unjustified "Business Deals" That Made Sense Only When Linked to Deferred Generic Entry

129. In total, Solvay paid tens of millions of dollars to Watson, Par, and Paddock to compensate each for agreeing to delay market entry. These large payments were unjustified, and would not have occurred if Watson, Par, and Paddock had not agreed to end the threat of earlier market entry.

130. Defendants touted the payments in their agreements as fees for "co-promotion" and "back-up manufacturing." These rationales were pretextual and meant to obscure the fact

that Solvay and the Generic Defendants had agreed to horizontally allocate the market for AndroGel. The payment of these "fees" was Defendants' mechanism for transferring from Solvay to Watson and Par/Paddock some of the monopoly profits that would be earned by Solvay during the period when generic entry was foreclosed. The co-promotion, back-up manufacturing, and other pretextual rationales for the payments were in truth unjustified, because they had little or no real value to Solvay, and in any event were worth far less than the millions of dollars Solvay paid to Watson and Par/Paddock pursuant to the agreements.

131. Solvay's co-promotion deals with Watson and Par are not independent and justifiable business transactions for at least the following reasons:

a. Prior to settlement discussions with Watson and Par, Solvay was not looking for co-promotion. Its 2006 business plan for AndroGel assumed "no co-promotion during the plan period," two prior AndroGel co-promotion efforts had been cancelled because they had "no significant impact" on sales trends, and a late 2005 analysis from a consulting firm concluded that future AndroGel co-promotion offered "little revenue upside."

b. Solvay's payments to Watson and Par far exceeded the value of any services provided.

c. Other terms of the co-promotion deals depart from industry standards. For example, unlike Solvay's previous AndroGel co-promotion agreements, Solvay cannot terminate the deal early if co-promotion does not improve AndroGel sales.

d. Before agreeing to the co-promotion deals, Solvay did not analyze how the Watson or Par co-promotion efforts would affect AndroGel sales, as it did before entering into earlier co-promotion agreements. Solvay instead examined the "Estimated Impact of Settlement" on Solvay's budget and accounted for co-promotion as a cost of settlement rather than a profitable business deal.

132. Solvay's back-up manufacturing deal with Paddock is not an independent and justifiable business transaction for at least the following reasons:

a. The back-up manufacturing deal guarantees Paddock $2 million per year for six years, regardless of whether Paddock ever manufactures AndroGel or ever becomes FDA-qualified to manufacture AndroGel.

b. Before entering into the back-up manufacturing deal, Solvay conducted no diligence on Paddock's manufacturing facilities. Solvay has paid Paddock $2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as back-up manufacturer until November 2008.

133. The agreements between Solvay and Watson, and Solvay and Par/Paddock, were and are anticompetitive and foreclosed the possibility of competition in the AndroGel market in exchange for settlement of the '894 patent suits and the large and unjustified payments from Solvay to the generics.

134. In 2011, Perrigo Company purchased all or part of the assets of Paddock. Upon completion of the asset purchase, Perrigo joined the ongoing unlawful course of conduct—i.e., the unlawful agreements, collusion, and conspiracy with respect to the suppression of generic competition for AndroGel. Perrigo did not withdraw from that conspiracy, but instead participated in it, including by abiding by the terms of the unlawful agreements, knowing that those agreements were entered into for an anti-competitive purpose, and continuing to receive the benefit of those agreements.

135. In 2012, Abbott, parent of Solvay, announced its plan to spin off most of its prescription drug business to a new entity, AbbVie. That plan came to fruition as of January 1, 2013. As successor to Abbot (Solvay), AbbVie has stepped into the shoes of Solvay with respect to the unlawful agreements.

136. In January of 2013, upon transition of the AndroGel business from Solvay to AbbVie, AbbVie joined the on-going conspiracy with respect to the suppression of competition in the market for generic AndroGel. AbbVie did not withdraw from the conspiracy, but instead

participated in it, including by abiding by the terms of the unlawful agreements, knowing that those agreements were entered into for an anti-competitive purpose, and continuing to receive the benefit of those agreements.

137. Had the Defendants settled the patent lawsuits in a lawful and pro-competitive manner, without Solvay making large and unjustified payments to the Generic Defendants, the Generic Defendants would have been allowed to enter the AndroGel market earlier than under the agreements at issue, thus saving Giant Eagle and its assignor millions of dollars.

M. Perrigo Launches its Generic Testosterone Gel

138. On January 31, 2013, the FDA approved Perrigo's generic 1.0% synthetic testosterone gel under NDA No. 203098. Unlike AndroGel, Perrigo's testosterone gel employs an isostearic acid penetration enhancer.[4] On July 23, 2014, the FDA assigned an AB-rating to Perrigo's testosterone gel.

139. Perrigo launched its AB-rated generic 1.0% synthetic testosterone gel on December 27, 2014.

N. The Unlawful Agreements to Suppress Generic Competition for AndroGel are On-Going and Continue to Cause Injury

140. To this day, AbbVie continues to sell AndroGel at supracompetitive prices and Giant Eagle, by and through its assignor, has been denied the lower prices that unrestrained generic competition would have permitted on the market. The lack of unrestrained generic competition is a direct and on-going result of the unlawful agreements among the Defendants. Given the success of Defendants' anticompetitive scheme, the lack of unrestrained generic competition for AndroGel is ongoing.

[4] The penetration enhancer in AndroGel is isopropyl myristate.

141. Since the unlawful agreements were made, Defendants' unlawful conduct in violation of the antitrust law has been on-going: payments have been made from Solvay/AbbVie to the Generic Defendants to compensate them for refraining from entering the market, the Generic Defendants have done their part by in fact refraining from entering the market, and Giant Eagle and its assignor have been and continue to be injured with each day that the unlawful agreements have been in effect.

O. Solvay's Patent Was Unlikely to Prevent Generic Competition for AndroGel

142. Before Solvay paid Watson and Par/Paddock for their agreements not to market their respective generic versions of AndroGel, Watson and Par/Paddock had amassed substantial evidence that their generic products did not infringe the formulation patent and argued that the patent was invalid and/or unenforceable.

143. Watson and Par/Paddock argued that the scope of the formulation patent was limited and that their products were outside the scope of the patent claims. They argued that their generic products did not infringe the patent, because their products contained ingredients that the patent did not cover, or amounts of ingredients were outside the amounts covered by the patent.

144. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed substantial evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of patented invention, in that Besins offered the invention for sale to Solvay in 1995—a fact that Solvay and Besins withheld from the Patent and Trademark Office.

- The patent was invalid as obvious under 35 U.S.C. § 103, because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods.

- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the "written description" requirement.

145. Watson and Par/Paddock also argued that the COC that changed the scope of some of the patent claims was invalid and/or did not apply to the pending litigation, which was filed before the certificate of correction issued.

146. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues and addressed others in claim construction briefing and expert reports.

147. Solvay bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent—in other words, that the generic products were within the scope of the patent claims. Solvay had not met its burden when the litigation ended in settlements.

148. Solvay was unlikely to prevent generic entry through its patent lawsuits. To do so, Solvay had to prove infringement by both Watson and Par/Paddock and also had to defeat each of the Generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock prevailed on any one of these issues, Solvay's formulation patent would not have prevented generic entry.

149. Recognizing the weakness of its patent claims and the large risk that its patent litigation would ultimately fail to prevent earlier generic entry, Solvay entered into agreements to pay Watson and Par/Paddock millions of dollars to refrain from entering the market until Solvay's preferred entry dates, rather than seeking injunctive relief or receiving a final judgment on its patent claims from the court.

VII. INTERSTATE COMMERCE

150. Defendants' efforts to restrain competition in the market for AndroGel and its generic equivalents have substantially affected interstate commerce.

151. At all material times, Defendant Solvay manufactured, promoted, distributed, and sold substantial amounts of AndroGel in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

152. At all material times, Defendant Solvay transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of AndroGel.

153. In furtherance of their efforts to restrain competition in the market for AndroGel and its generic equivalents, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VIII. RELEVANT MARKET AND MARKET EFFECTS

154. The relevant product market is AndroGel and its generic bioequivalents rated "AB" by the FDA. AndroGel would not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of AndroGel. The relevant geographic market is the United States. Solvay's market share in the relevant product and geographic markets was 100% until at least Perrigo's December 27, 2014 launch of an AB-rated generic. Even assuming Solvay began to lose market share with the launch of that product, by preventing other generics from entering the market until 2015 and 2016, Solvay was still able to slow the erosion of its market share and continue to charge supracompetitive prices.

155. At all relevant times, Defendant Solvay had market power over the market for AndroGel because it had the power to maintain the price of AndroGel at supracompetitive levels without losing substantial sales. Defendant Solvay needed to control only AndroGel and its AB-

rated generic equivalents, and no other products, in order to maintain the price of AndroGel profitably at supracompetitive levels.

156. Defendant Solvay sold AndroGel at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins. Defendant Solvay, at all relevant times, enjoyed high barriers to entry with respect to AndroGel.

157. Prior to settlement of the '894 patent lawsuits and execution of agreements between Solvay and the Generic Defendants, Solvay and Watson were potential competitors.

158. By entering into their agreements, Solvay and Watson eliminated the risk that (a) Watson would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Watson would have prevailed in the patent litigation and marketed generic AndroGel before 2015; or (c) Solvay and Watson would have agreed to settle their patent litigation on terms that did not compensate Watson for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

159. Prior to settlement, Solvay and Par/Paddock were potential competitors. By entering into their agreement, Solvay and Par/Paddock eliminated the risk that (a) Par/Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel well before 2015; or (c) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

160. Defendants eliminated this potential competition by entering into agreements to settle the patent litigation that provided large and unjustified payments from Solvay to Watson and Par/Paddock in exchange for Watson and Par/Paddock refraining from marketing generic

AndroGel until Solvay's preferred entry dates. These agreements, which delayed potential competition, were based not on the strength of Solvay's patent, but on the large and unjustified payments that Solvay provided to Watson, and Par/Paddock in exchange for delayed generic entry dates. Absent those payments, Watson and Par/Paddock would not have agreed to settle the '894 patent litigation and refrain from competing until the generic entry dates that Solvay demanded.

161. Moreover, absent the large and unjustified payments that Solvay agreed to provide, generic competition to AndroGel would have occurred before 2015 because (a) Watson and/or Par/ Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (b) Solvay would not have prevailed against each of Watson and Par/Paddock in the patent litigations; or (c) Solvay would have agreed to settle the patent litigation on terms that did not compensate Watson and Par/Paddock for abstaining from selling AB-rated generic AndroGel, but would have provided for generic entry earlier than 2015.

162. Earlier entry of generic AndroGel would have resulted in a fundamental shift in the market from Solvay's branded AndroGel to lower-priced AB-rated generic versions of AndroGel. Even assuming the December 27, 2014 launch of Perrigo's AB-rated generic product began this process, it would have proceeded more quickly if other generic products were on the market, such that even after December 27, 2014, Solvay through its agreements with Watson and Par/Paddock extended the period it could charge supracompetitive prices by restraining generic competition.

163. Through their anticompetitive conduct, Defendants have (a) delayed generic entry and (b) retained those potential consumer savings for themselves.

164. Through the overarching anticompetitive scheme, including the exclusion payment agreements, Defendants knowingly and intentionally conspired to maintain and enhance Solvay's monopoly power in the relevant market by blocking and delaying market entry of AndroGel. The large, unjustified, and unlawful exclusion payment agreements between Defendants allocated 100% of the Androgel and its generic bioequivalent rated "AB" market in the United States, and delayed the sales of competing generic AndroGel products for as long as nine years or more.

165. The goal, purpose, and/or effect of the agreements was to maintain and extend Solvay's monopoly power in the United States market for AndroGel and its generic bioequivalents rated "AB". The exclusion payment agreements prevented and/or delayed generic competition to AndroGel and enabled Solvay to continue charging supracompetitive prices for AndroGel without a loss of sales sufficient to make those prices unprofitable.

166. Defendants specifically intended that the exclusion payment agreements would maintain Solvay's monopoly power in the relevant market, and injured Giant Eagle and its assignor.

167. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain Solvay's monopoly power, Giant Eagle and its assignor paid artificially inflated prices for AndroGel, as described herein, and were harmed as a result.

168. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. The filing of the '894 patent and/or the use of exclusion payments to prevent generic competition, such as Defendants have done, distorts the

careful balance achieved by the Hatch-Waxman Act by eliminating generic companies' incentives to compete.

169. Exclusion payments are not a natural byproduct of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies.

170. Through its improper Orange Book listing, settlement of patent litigation, and large and unjustified exclusion payment settlements, Solvay bought protection from competition not contemplated or authorized by the Hatch-Waxman Act—with consumers paying the price for its anticompetitive conduct.

IX. ANTITRUST IMPACT

171. During the relevant period, Giant Eagle, with and through its assignor, purchased substantial amounts of AndroGel directly from Solvay. As a result of Defendants' illegal agreements as described herein, Giant Eagle and its assignor were compelled to pay, and did pay, artificially inflated prices for their synthetic testosterone gel requirements. This injury is of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' acts unlawful.

172. As a consequence of Defendants' unlawful conduct and overarching scheme, Giant Eagle, with and through its assignor, sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

173. Defendants' unlawful conduct threatens continuing loss and damage to Giant Eagle and its assignor unless enjoined by this Court.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U. S. C. § 1
(Agreement in restraint of trade against Solvay and Watson/Actavis)

174. Giant Eagle hereby incorporates each preceding paragraph as though fully set forth herein.

175. This claim is asserted against Solvay and Watson/Actavis.

176. On or about September of 2006, Solvay and Watson entered into the patent litigation settlement agreement and S/W Co-Promotion Agreement as described herein, which collectively are a continuing illegal contract, combination, and conspiracy in restraint of trade under which Solvay agreed to pay Watson substantial financially-valuable consideration in exchange for Watson's agreement to delay bringing its generic version of AndroGel to the market. Solvay's payment to Watson in exchange for Watson's agreement to settle the patent litigation and delay generic entry was large and unjustified.

177. The purposes and effects of Solvay and Watson's agreements were to: (a) allocate 100 percent of the market for synthetic testosterone gel in the United States to Solvay; (b) prevent and/or delay the sale of generic versions of AndroGel in the United States, thereby protecting AndroGel from generic competition for nine years or more; and (c) fix the price for synthetic testosterone gel at supracompetitive levels.

178. These agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

179. Solvay and Watson/Actavis are liable for the creation, maintenance, and enforcement of the patent litigation settlement agreement and S/W Co-Promotion Agreement under the Rule of Reason as articulated in *FTC v. Actavis, Inc.*, 570 U.S. ___ (2013).

180. There are and were no legitimate, nonpretextual, procompetitive business justifications for the anticompetitive components of these agreements as described herein that outweigh their anticompetitive effects. Even if there were some such justifications, the anticompetitive components of the agreements were not necessary to achieve such a purpose, nor were they the least restrictive means of achieving any such purported justifications.

181. As a direct and proximate result of Solvay, Watson, and Actavis' concerted, illegal, and anticompetitive conduct as described herein, Giant Eagle and its assignor suffered antitrust injury as described above.

CLAIM II: VIOLATION OF 15 U. S. C. § 1
(Agreement in restraint of trade against Solvay and Par)

182. Giant Eagle hereby incorporates each preceding paragraph as though fully set forth herein.

183. This claim is asserted against Solvay and Par.

184. On or about September of 2006 and at times prior to formal execution, Solvay and Par entered into the patent litigation settlement agreements and the S/PAR Co-Promotion Agreement as described herein, which collectively are a continuing illegal contract, combination, and conspiracy in restraint of trade under which Solvay agreed to pay Par substantial financially-valuable consideration in exchange for Par's agreement to delay bringing its generic version of AndroGel to the market. Solvay's payment to Par in exchange for Par's agreement to settle the patent litigation and delay generic entry was large and unjustified.

185. The purposes and effects of Solvay and Par's agreements were to: (a) allocate 100 percent of the market for synthetic testosterone gel in the United States to Solvay; (b) prevent and/or delay the sale of generic versions of AndroGel in the United States, thereby protecting

AndroGel from generic competition for nine years or more; and (c) fix the price for synthetic testosterone gel at supracompetitive levels.

186. These agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

187. Solvay and Par are liable for the creation, maintenance, and enforcement of these agreements under the Rule of Reason as articulated in *FTC v. Actavis, Inc.*, 570 U.S. ___ (2013).

188. There are and were no legitimate, nonpretextual, procompetitive business justifications for the anticompetitive components of these agreements as described herein that outweigh their anticompetitive effects. Even if there were some such justifications, the anticompetitive components of these agreements were not necessary to achieve such a purpose, nor were they the least restrictive means of achieving any such purported justifications.

189. As a direct and proximate result of Solvay and Par's concerted, illegal, and anticompetitive conduct as described herein, Giant Eagle and its assignor suffered antitrust injury as described above.

CLAIM III: VIOLATION OF 15 U. S. C. § 1
(Agreement in restraint of trade against Solvay, Paddock, and Perrigo)

190. Giant Eagle hereby incorporates each preceding Paragraph as though fully set forth herein.

191. This claim is asserted against Solvay, Paddock, and Perrigo.

192. On or about September of 2006 and at times prior to formal execution, Solvay and Paddock entered into the patent litigation settlements agreements and S/PAD Back-Up Supply Agreement as described herein, which is a continuing illegal contract, combination, and conspiracy in restraint of trade under which Solvay agreed to pay Paddock substantial financially-valuable consideration in exchange for Paddock's agreement to delay bringing its

generic version of AndroGel to the market. Solvay's payment to Paddock in exchange for Paddock's agreement to settle the patent litigation and delay generic entry was large and unjustified.

193. The purposes and effects of Solvay and Paddock's agreements were to: (a) allocate 100 percent of the market for synthetic testosterone gel in the United States to Solvay; (b) prevent and/or delay the sale of generic versions of AndroGel in the United States, thereby protecting AndroGel from generic competition for nine years or more; and (c) fix the price for synthetic testosterone gel at supracompetitive levels.

194. These agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

195. Solvay, Paddock, and Perrigo are liable for the creation, maintenance, and enforcement of these agreements under the Rule of Reason as articulated in *FTC v. Actavis, Inc.*, 570 U.S. ___ (2013).

196. There are and were no legitimate, nonpretextual, procompetitive business justifications for the anticompetitive components of these agreements as described herein that outweigh their anticompetitive effects. Even if there were some such justifications, the anticompetitive components of these agreements were not necessary to achieve such a purpose, nor were they the least restrictive means of achieving any such purported justifications.

197. As a direct and proximate result of Solvay, Paddock, and Perrigo's concerted, illegal, and anticompetitive conduct as described herein, Giant Eagle and its assignor suffered antitrust injury as described above.

CLAIM IV: VIOLATION OF 15 U. S. C. § 1
(Agreement in restraint of trade against all Defendants)

198. Giant Eagle hereby incorporates each preceding Paragraph as though fully set forth herein.

199. This claim is asserted against all Defendants.

200. By entering into co-promotion and back-up manufacturing agreements, Solvay orchestrated and brokered an overarching agreement with, between, and among Watson and Par/Paddock not to compete with each other or with Solvay, which constituted a continuing illegal contract, combination, and conspiracy in restraint of trade. Solvay agreed to pay Watson and Par/Paddock substantial, financially-valuable consideration in exchange for their respective agreements with Solvay, and between and among each other, to delay bringing their generic versions of AndroGel to the market until 2015. Solvay's payments to Watson and Par/Paddock in exchange for their agreement to settle the patent litigation and delay generic entry were individually and collectively large and unjustified.

201. The purpose and effect of Defendants' overarching agreements were to: (a) allocate 100 percent of the market for synthetic testosterone gel in the United States to Solvay; (b) prevent and/or delay the sale of generic versions of AndroGel in the United States, thereby protecting AndroGel from generic competition for nine years or more; and (c) fix the price for synthetic testosterone gel at supracompetitive levels.

202. Defendants' overarching agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

203. Defendants are *per se* liable for the creation, maintenance, and enforcement of their overarching agreement.

204. Alternatively, Defendants are liable for the creation, maintenance, and enforcement of their overarching agreement under the Rule of Reason.

205. There are and were no legitimate, nonpretextual, procompetitive business justifications for the Defendants' overarching agreement as described herein that outweighs its anticompetitive effects. Even if there were some such justifications, the Defendants' overarching agreement was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justifications.

206. As a direct and proximate result of Defendants' concerted, illegal, and anticompetitive conduct as described herein, Giant Eagle and its assignor suffered antitrust injury as described above.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Giant Eagle prays for judgment against Defendants and for the following relief:

A. A judgment for three times its actual damages, as determined by a jury at trial;

B. Permanent injunctive relief enjoining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the effects of their prior conduct;

C. The costs of this suit, including reasonable attorneys' fees as provided by law; and

D. Such other and further relief as the Court deems just and appropriate.

XII. JURY DEMAND

Giant Eagle demands a trial by jury of all issues so triable.

Dated: May 8, 2015

Respectfully submitted,

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